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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 226,046 | 01/05/1999 | STEVEN M. REPPER | 10217-250003 | 1585 |

26363 7590 03/11/2003

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BOSTON, MA 02110

EXAMINER

PAK, MICHAEL D

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1646

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/226,046

Applicant(s)

REPPERT ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33, 35, 53, 78 and 80-89 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 86-89 is/are allowed.
- 6) ☒ Claim(s) 33, 35, 53, 78, 80-85 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

DETAILED ACTION

Response to Amendment

1. Applicant's response to office action filed 29 October 2002 (Paper No. 29) has been received.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 29 October 2002 (Paper No. 29), have been fully considered but they are not found persuasive.

Claim Rejections - 35 USC § 112

Claims 33, 35, 53, 78, and 80-85 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that that *University of California v. Eli Lilly and Co.* is drawn to cDNA and not methods. However, the essential feature of the method claim is using the specific human melatonin receptor consisting of SEQ ID NO:12 and thus the ability to envision the receptor is essential for the description of the claimed method. The

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claims encompass generic variants of high affinity melatonin receptor protein whose function is not defined and metes and bounds of the function is not clear.

Applicants argue that "substantially identical" is defined on page 5 of the specification. However, the term encompasses generic variants whose function is not defined and the metes and bounds of the function is not clear. As defined on page 5, limitless substitutions, deletions, and additions may be made which does not provide a metes and bounds of the structure.

4. Claims 33, 35, 53, 78 and 80-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33 and 35 recite or encompass the term "high affinity melatonin receptor" but the metes and bounds of the term is not clear. Applicant submitted another review article by Dubocovich published in 1988 which differentiates the difference between the species of high affinity receptor and lower affinity receptor using different compounds. However, applicant did not address the discrepancy on page 182 of Dubocovich et al.(2000) that teaches that high affinity melatonin receptor has an affinity(KD?) of 30-300 pM but the figure 1 on page 183 indicate that MT3 which is the low affinity melatonin receptor is 300 pM- 2 nM which is confusing because it is not clear if you have a 300 pM melatonin receptor whether it is a high affinity or low affinity melatonin receptor. The later Dubocovich et al.(2000) reference appears to have the retrospective using known receptors of both molecular cloning and traditionally identified receptors in

tissue cells while the earlier reference does not address the cloning products affinity. It is suggested that definition of the term be clearly elucidated in the response which indicates the metes and bounds of the term. It is also suggested that claim limitation which differentiates a high affinity melatonin receptor from a low affinity melatonin receptor be made with the specific reference in the specification for the support. Claims encompass any proteins of no defined structure and the functional clarification is critical for a claim encompassing a large of genus of molecules.

Claim 53 and 78 recite or encompass the term "substantially identical" but the metes and bounds of the term is not clear. It is not clear when the melatonin receptor is substantially identical to SEQ ID NO:12 when it is not substantially identical. Applicants argue that page 5 of the specification define the term "substantially identical". However, as defined on page 5, limitless substitutions, deletions, and additions may be made which does not provide a metes and bounds of the structure.

5. Claims 86-89 are allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 703-305-7038.

The examiner can normally be reached on Monday-Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Michael D. Pak

Michael Pak

Primary Patent Examiner

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05 March 2003